DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 26, 2014

Sunmas (H.K.) Trading Limited
c/o Diana Hong
Mid-Link Consulting Co., Ltd
13th Floor, Wah Kit Commercial Centre,
302 Des Voeux Road Central, G.P.O. Box 2878
Hong Kong, China

Re: K133979
Trade/Device Name: TENS Models SM9066, SM9088, SM9090, SM9098, SM9128, and SM9198
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: July 26, 2014
Received: July 29, 2014

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133979

Device Name
TENS
Model: SM9066, SM9088, SM9090, SM9098, SM9128 and SM9198

Indications for Use *(Describe)*

It is intended to be used for temporary relief of pain associated with sore and aching muscle in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S
Date: 2014.08.26 22:12:08 -04'00'

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510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1. Date of Preparation: Nov 20, 2013

2. Sponsor

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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: TENS
Proposed Device Model: SM9066, SM9088, SM9090, SM9098, SM9128 and SM9198
Common Name: Stimulator, Nerve, Transcutaneous, Over-the-Counter
Classification: II
Product Code: NUH
Regulation Number: 21 CFR 882.5890
Review Panel: Neurology
Intended Use Statement:
It is intended to be used for temporary relief of pain associated with sore and aching muscle in the

shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

5. Predicate Device Identification

510(k) Number: K102598
Product Name: JQ-5C
Manufacturer: Hi-Dow International, Inc

6. Device Description

The TENS is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain.

The TENS consists of LCD, Control Key, Switch, Battery, Output jack and USB port, its accessories includes electrode, electrode cable, USB wire and Battery charger. Only the electrode pads cleared in submission, K092546, are to be used with this device

The proposed device has six models: SM9066, SM9088, SM9090, SM9098, SM9128 and SM9198. The six models have the same design principle and functional components, including battery, LCD, Control Key, Switch, channel number and USB port and accessories. The difference between the six models specifically expressed in the battery specification, LCD dimension, the position of Control key, Switch, and USB port on the proposed device, PCB(Printed Circuit Board) dimension and the number of Output jack numbers.

Table 3-1 the difference between proposed device and predicate device

ITEM	Proposed device	Predicate device JQ-5C
Power source	DC 3.7V Lithium Battery	DC 3.7V Lithium Battery
Waveform	Pulse, biphasic	Pulse, biphasic
Shape	Rectangular	Rectangular
Pulse Duration(Pulse width)	100μs	100μs
Net Charge	0 μC@500Ω, balanced waveform	0 μC@500Ω, balanced waveform
Same between proposed device and predicate device: Same power source, waveform, shape, pulse duration and net charge.		
Maximum Output Voltage	42V±10%@500Ω	62.4V@500Ω
	84V±10%@2kΩ	79.2V@2.2kΩ
	140V±10%@10kΩ	84V%@10kΩ
Maximum Output Current	84mA±10%@500Ω	124.8mA@500Ω
	42mA±10%@2kΩ	39.65mA@2.2kΩ
	14mA±10%@10kΩ	8.4 mA@10kΩ
Differences between proposed device and predicate device: The maximum output voltage of the proposed device is covered by that of the predicate device; correspondingly the maximum output current of the proposed device is also covered by that of the predicate device. Meanwhile considering the ±10% deviation of each value, the maximum output voltage value and maximum output current value of the proposed device could be considered to be accepted and substantially equivalent to that of the predicate devices.		
Frequency	68Hz,12.5~55.5 Hz, 1.17 Hz, 5.8 Hz, 108 Hz, 29 Hz	Similar
Pulse period, msec	14.7 ms, 18~80ms; 850ms; 172ms, 9.2ms, 16.9ms	Similar
Similarities between proposed device and predicate device: Per IEC 60601-2-10, 51.104, it states that *for equipment intended for therapeutic applications: with a load resistance of 500Ω the output current r.m.s shall not exceed the limit of 50mA in case of Frequency ⩽400Hz*; and the RMS output current of the proposed device which is calculated based on the frequency parameters meets the IEC 60601-2-10 requirements, therefore although there is slight difference on pulse period and frequency between proposed device and predicate device, the two parameter is considered to be acceptable and substantially equivalent to the predicate devices		
Stimulus delivered for mode	Similar	Similar
Similar stimulus delivery: Although there are no graphical drawings to assist in the description of the stimulus delivered in each mode for proposed device and predicate device, based on the SE discussion section we could see that this stimulus delivered from proposed device and predicate device are similar.; In other words, this stimulus delivery between proposed device and predicate device which adopt the same fundamental output technology will offer the similar treatment		

effect. Therefore, this item is considered to be substantially equivalent.

Comparison Summary:
The proposed device is compared to the predicate device in terms of power source, waveform, shape, pulse duration, net charge, frequency, pulse period and stimulus delivered of each mode. Based on the analysis of similar/different points between the proposed device and predicate device, the proposed device is finally considered to be substantially equivalent to the predicate device; and the differences will not affect the safety and effectiveness of the proposed device.

7. Biocompatibility Summary

The patient-contact component of the proposed device is the GMDASZ TENS Electrodes. The biocompatibility of the GMDASZ TENS Electrodes has been demonstrated in K092546. It was tested for cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), and irritation sensitivity (ISO 10993-10) with the test result in K092546. The biocompatibility of predicate device was demonstrated in term of cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), and irritation sensitivity (ISO 10993-10) in K102598. Therefore the biocompatibility of the proposed device is considered to be substantially equivalent to that of the predicate device (K102598).

8. Usability Discussion

In order to validate the usability performance of TENS device for US market, the sponsor organized a usability study in America. The study focused on the labeling information to support the safe and effective use of the proposed device.

The usability study demonstrated that the final version of the labeling for the TENS, were well understood by a variety of “patients”, and provided sufficient information for safe and proper use of the device.

9. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all proposed design specifications. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1: 1988+ A1: 1991+ A2: 1995, Medical Electrical Equipment- Part 1: General requirements for safety.
IEC 60601-1-2: 2007, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility- Requirements and tests

IEC 60601-2-10: 1987/A1: 2001, Medical electrical equipment, Part 2: Particular requirements for the safety of nerve and muscle stimulators.

10. Substantially Equivalent Conclusion

The electrical stimulation provided by a series of model SM9066, SM9088, SM9090, SM9098, SM9128 and SM9198 are similar to the commonly employed TENS devices that have been cleared for marketing without prescription labeling.

These models have the same intended use and the similar technological characteristics as those OTC predicates. Moreover, verification and validation tests contained in this submission demonstrate that the difference in these models still maintain the same safety and effectiveness as that of the cleared devices.

In other words, those engineering differences do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

The adequate guidance to the user on electrode application and electrode placement are presented in the User Manual; the information is used to insure the electrode can be used safely and effectively.

We believe that there are no new safety or effectiveness issues concerning this device to be introduced. Technological characteristics, features, specifications, materials and intended uses of the series of model SM9066, SM9088, SM9090, SM9098, SM9128 and SM9198 are substantially equivalent to the quoted predicated devices.

The differences that exist between the devices are insignificant in the terms of safety or effectiveness. The proposed device, TENS, Model of SM9066, SM9088, SM9090, SM9098, SM9128 and SM9198 is determined to be Substantially Equivalent (SE) to the predicate device, K102598, in respect of safety and effectiveness.